



CASE 33319

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

STEMPER

INTERNATIONAL APPLICATION NO: PCT/EP2004/009321

FILED: 19 AUGUST 2004

U.S. APPLICATION NO: 10/568,329

35 USC §371 DATE: 15 FEBRUARY 2006

FOR: PROCESS FOR THE PREPARATION OF RECOMBINANT

POLYPEPTIDES

MS: Amendment Commissioner for Patents PO Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

These references were cited in search reports in corresponding and related applications (10/568,337, 10/568,332 & 10,568,329). Copies of these references and the search report are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Aftorney for Applicants Reg. No. 34,940

Novartis Corporate Intellectual Property One Health Plaza, Building 104 East Hanover, NJ 07936-1080 (609) 627-8507

Date: 6/30/2006

- 2 -

FORM PTO-1449 (REV. 7-85) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. 33314 APPLICATION NO.

APPLICANT
WINDISCH ET AL.
FILING DATE
FEBRUARY 13, 2006

Group

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE |
|---------------------|----|-----------------|---------|------------------|-------|----------|-------------|
| HUIDE | AA | 5,710,027 | 1/20/98 | Hauptmann et, al | | | |
| | AB | 2003/0026805 | 2/6/03 | Athwal et,al. | | | |
| | AC | 5,648,237 | 7/15/97 | Paul J. Carter | | | |
| | AD | 4,680,262 | 7/14/87 | Bochner et, al. | | | |
| | AE | 2004/151695 | 8/5/04 | Kwon et al. | | | |
| | AF | | | | | | |
| | AG | | | | | | <u> </u> |
| | АН | | | | | | |
| | Al | | | | | | · |
| | AJ | | | | | | |
| | AK | | | | | | |
| | AL | | | | | | |

FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | DATE | OFFICE | CLASS | SUBCLASS | TRAN YES | SLATION NO |
|--------|-----------------|---------|----------------------------|-------|----------|-------------|---------------|
| AM | WO 89/00201 | 1/12/89 | University of Dundee | | | | |
| AN | WO 03/004599 | 1/16/03 | Insight strategy & Mkt Ltd | | | | |
| AO | EP 0 974 654 | 1/26/00 | Mitsui Chemicals Inc | | · | | |
| AP | WO 01/57217 | 8/9/01 | Choi Ki Doo et al. | | | | |
| AQ | | | | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| AR | BOURDINEAUD J P ET AL: "Cytoplasmic and Periplasmic Expression of a Synthetic gene for Ferredoxin in Escherichia-coli", Biochimie (Paris), vil.72, no. 6-7, 1990, pages 407-415, XP002316190 |
|--------|--|
| AS | WEICKERT M J ET, AL: "Optimization of Heterologous Protein Production in Escherichia Coli", Current opinion in Biotechnology. London, GB, Vol. 7, no. 5, 1996, pages 494-499, XP000995157 |
| AT | HUMPHREYS D P ET AL: "High- LEVEL Periplasmic Expression in Escherichia coli Using a Eukaryotic Signal Peptide: Importance of Codon usage at the 5' end of the coding sequence" Protein expression and purification academic press, San Diego, CA, US, Vol. 20, no.2, November 2000, pgs |
| | DATE CONCIDENCE |

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

FORM PTO-1449 (REV. 7-85)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

ATTY. DOCKET NO. 33314 APPLICATION NO.

APPLICANT WINDISCH ET AL. **FILING DATE FEBRUARY 13, 2006**

Group

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

| ADEN | | |
|----------|----|---|
| Ĺ | DA | MATSUDA A ET AL:" Molecular Cloning and Structure of the Gene for 7-beta-4 Carboxybutanamidocephalosporanic-acid acylase from a pseudomonas strain", Journal of Bateriology, vol. 163, no. 3, 1985, pages1222-1228, XP002316191 |
| C | ов | FRENCH C ET AL:" Development of a simple method for the recovery of recombinant proteins from the escherichia coli periplasm" Enzyme and Microbial Technology, Stoneham, MA, US, Vol. 19, no. 5, 1996, pages 332-338, XP000886796 |
| С | С | DALMORA S ET AL: "Analysis of recombinant human growth hormone directly in osmotic shick fluids" Journal of Chromotography A, Elsevier Science, NL., Vol.s 782, no. 2, 10 October 1997, pages 199-210, XP004096275 |
| | סכ | ANDERSON D C ET AL: " Production technologies for monoclonal antibodies and their fragments", Current opinion in Biotechnology, Vol 15, No. 5, October 2004, Pages 456-462 |
| С | DE | DE OLIVEIRA J E ET AL: "High-yeild purification of biosynthetic human growth hormone secreted in Escherichia coli periplasmic space" Journal of Chromatogrpahy A, Elsevier Science, NL. Vol. 852, no.2 13, Aug 1999, pgs 441-450 |
| С | OF | HANNIG G ET AL:" Strategies for optimizing heterologous protein expression in Escherichia coli", Trends in Biotechnology, Vol. 16, no. 2., February 1998, pages 54-60, XP004107042 |
| | og | MIDDLEBERG A P J: "Process-scale disruption of microorganisms" Biotechnology Advances, Vol. 13, no.3 1995, pages 491-551, XP004045404 |
| С | ЭН | BANEYX F: Recombinant protein expression in Escherichia coli" current opinion in Biotechnology, vol 10, no. 5, October 1999, pgs 411-421, XP001041299 |
| С | DI | HART R A ET AL: "Large scale, in situ isolation of periplasmic IGF-I from E. Coli", Bio Technology, Vol. 12, November 1994, pages 1113-1117, XP001153305 |
| С | DJ | |
| С | ж | |
| D | DL | · · · · · · · · · · · · · · · · · · · |
| D | М | |
| D | N | |
| EXAMINER | | DATE CONSIDERED |

*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.